



K963179

GE Medical Systems

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USA

NOV - 7 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

- ° This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- ° Identification of Submitter

Larry A. Kroger, Ph.D., 414-544-3894, August 2, 1996

- ° Identification of the Product

Signa SP Magnetic Resonance System - Optional Accessories

Manufactured by: GE Medical Systems
3200 N. Grandview Blvd.
Waukesha, WI 53188

- ° Marketed Devices

The Signa SP Magnetic Resonance System with optional accessories is substantially equivalent to the currently marketed Signa SP System.

- ° Device Description

The Signa SP System employs an open magnet configuration which helps to reduce patient anxiety, increases patient positioning options and allows easy access to the patient. The Scan Plane Pointer accessory is useful in acquiring MR images relative to the physical orientation of the patient. The images may then be displayed to the operator and on a screen at table side.

- ° Indications for Use

The Signa SP System optional accessories are indicated for use as follows:

- The Scan Plane Pointer facilitates localization of the scanning planes.
- The side entry patient support access feature and the Patient Imaging Chair allows multiple patient positions enabling imaging exams of dynamic joints (such as knees and shoulders) and loaded spine studies.
- The use of MR Imaging during interventional procedures using common devices such as fine needles and suction.



SUMMARY OF SAFETY AND EFFECTIVENESS

- **Comparison with Predicate**

The Signa SP Magnetic Resonance System with optional accessories, namely the Patient Support Chair, side docking of the patient support table and the Scan Plane Pointer give more imaging functionality.

- **Summary of Studies**

The Signa SP optional accessories was evaluated to the appropriate NEMA performance standards as well as the IEC 601-1 International medical equipment safety standard. Evaluation testing confirmed accuracy statements in the User Manual.

- **Conclusions**

It is the opinion of GE that the Signa SP optional accessories is substantially equivalent to the Signa SP Systems. The optional accessories do not result in any new potential hazards.